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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

CELGENE CORPORATION,

Plaintiff,

v.

**LOTUS PHARMACEUTICAL CO., LTD.
and ALVOGEN PINE BROOK, LLC,**

Defendants.

Civil Action No. _____

**COMPLAINT FOR
PATENT INFRINGEMENT**

(Filed Electronically)

Plaintiff Celgene Corporation (“Celgene”), by its undersigned attorneys, for its Complaint against defendants Lotus Pharmaceutical Co., Ltd. (“Lotus”) and Alvogen Pine Brook, LLC (“Alvogen” together with Lotus, “Defendants”), alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) No. 210480 (“Defendants’ ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to commercially market generic versions of Celgene’s 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg REVLIMID[®] drug products prior to the expiration of United States Patent Nos. 5,635,517 (“the ’517 patent”); 6,315,720 (“the ’720

patent”); 6,561,977 (“the ’977 patent”); 6,755,784 (“the ’784 patent”); 7,189,740 (“the ’740 patent”); 7,465,800 (“the ’800 patent”); 7,855,217 (“the ’217 patent”); 7,968,569 (“the ’569 patent”); 8,315,886 (“the ’886 patent”); 8,404,717 (“the ’717 patent”); 8,530,498 (“the ’498 patent”); 8,626,531 (“the ’531 patent”); 8,648,095 (“the ’095 patent”); 9,056,120 (“the ’120 patent”); 9,101,621 (“the ’621 patent”); and 9,101,622 (“the ’622 patent”), all owned by Celgene (collectively, “the patents-in-suit”).

The Parties

2. Plaintiff Celgene is a biopharmaceutical company committed to improving the lives of patients worldwide. Celgene focuses on, and invests heavily in, the discovery and development of products for the treatment of severe and life-threatening conditions. Celgene is a world leader in the treatment of many such diseases, including cancer. Celgene is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 86 Morris Avenue, Summit, New Jersey 07901.

3. On information and belief, Defendant Lotus is a corporation organized and existing under the laws of Taiwan, maintaining its headquarters at 15F, No. 149, Sec 3, Xin Yi Road, Da An District, Taipei City 106, Taiwan.

4. On information and belief, Defendant Alvogen is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 10 Bloomfield Ave, Building B, Pine Brook, NJ 07058.

5. On information and belief, Alvogen Lux Holdings S.á.r.l. is the parent corporation of Alvogen Group, Inc., which is the parent corporation of Alvogen.

6. On information and belief, Alvogen Group, Inc. is the majority shareholder of Lotus.

7. “Through its majority shareholder Alvogen [Group, Inc.], Lotus has access to markets in the USA.” See <http://www.lotuspharm.com/company/> (last accessed August 25, 2017).

The Patents-in-Suit

8. On June 3, 1997, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’517 patent, entitled, “Methods of Reducing TNF α Levels with Amino Substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisindolines,” to Celgene as assignee of inventors George W. Muller, David I. Stirling, and Roger Shen-Chu Chen. A copy of the ’517 patent is attached hereto as Exhibit A.

9. On November 13, 2001, the USPTO duly and lawfully issued the ’720 patent, entitled, “Methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug,” to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the ’720 patent is attached hereto as Exhibit B.

10. On May 13, 2003, the USPTO duly and lawfully issued the ’977 patent, entitled, “Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated,” to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the ’977 patent is attached hereto as Exhibit C.

11. On June 29, 2004, the USPTO duly and lawfully issued the ’784 patent, entitled, “Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated,” to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the ’784 patent is attached hereto as Exhibit D.

12. On March 13, 2007, the USPTO duly and lawfully issued the '740 patent, entitled "Methods of Using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the Treatment and Management of Myelodysplastic Syndromes" to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '740 patent is attached hereto as Exhibit E.

13. On December 16, 2008, the USPTO duly and lawfully issued the '800 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '800 patent is attached hereto as Exhibit F.

14. On December 21, 2010, the USPTO duly and lawfully issued the '217 patent, entitled, "Polymorphic Forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee of the inventors Markian S. Jaworsky, Roger Shen-Chu Chen, and George W. Muller. A copy of the '217 patent is attached hereto as Exhibit G.

15. On June 28, 2011, the USPTO duly and lawfully issued the '569 patent, entitled, "Methods For Treatment of Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '569 patent is attached hereto as Exhibit H.

16. On November 20, 2012, the USPTO duly and lawfully issued the '886 patent, entitled, "Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated," to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '886 patent is attached hereto as Exhibit I.

17. On March 26, 2013, the USPTO duly and lawfully issued the '717 patent, entitled "Methods of Treating Myelodysplastic Syndromes Using Lenalidomide" to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '717 patent is attached hereto as Exhibit J.

18. On September 10, 2013, the USPTO duly and lawfully issued the '498 patent, entitled, "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl) piperidine-2,6-dione," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '498 patent is attached hereto as Exhibit K.

19. On January 7, 2014, the USPTO duly and lawfully issued the '531 patent, entitled, "Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated," to Celgene as assignee of the inventors Bruce A. Williams and Joseph K. Kaminski. A copy of the '531 patent is attached hereto as Exhibit L.

20. On February 11, 2014, the USPTO duly and lawfully issued the '095 patent, entitled, "Methods For Treating Multiple Myeloma Using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione In Combination With Proteasome Inhibitor," to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '095 patent is attached hereto as Exhibit M.

21. On June 16, 2015, the USPTO duly and lawfully issued the '120 patent, entitled "Methods of Treating Myelodysplastic Syndromes with a Combination Therapy Using Lenalidomide and Azacitidine" to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the '120 patent is attached hereto as Exhibit N.

22. On August 11, 2015, the USPTO duly and lawfully issued the '621 patent, entitled, "Methods For Treating Multiple Myeloma With 3-(4-amino-1-oxo-1,3-dihydro-

isoindol-2-yl)-piperidine-2,6-dione After Stem Cell Transplantation,” to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the ’621 patent is attached hereto as Exhibit O.

23. On August 11, 2015, the USPTO duly and lawfully issued the ’622 patent, entitled, “Methods For Treating Newly Diagnosed Multiple Myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione In Combination With Dexamethasone,” to Celgene as assignee of the inventor Jerome B. Zeldis. A copy of the ’622 patent is attached hereto as Exhibit P.

The REVLIMID[®] Drug Product

24. Celgene holds an approved New Drug Application (“NDA”) under Section 505(a) of the Federal Food Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 355(a), for lenalidomide capsules (NDA No. 21-880), which it sells under the trade name REVLIMID[®]. The claims of the patents-in-suit cover, *inter alia*, lenalidomide, solid forms of lenalidomide, pharmaceutical compositions containing lenalidomide, and systems and methods of use and administration of lenalidomide or pharmaceutical compositions containing lenalidomide.

25. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to REVLIMID[®].

26. The labeling for REVLIMID[®] instructs and encourages physicians, pharmacists, and other healthcare workers and patients to administer REVLIMID[®] according to one or more of the methods claimed in the patents-in-suit.

Jurisdiction and Venue

27. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

28. This Court has personal jurisdiction over Alvogen by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Alvogen's principal place of business is in Pine Brook, New Jersey. On information and belief, Alvogen is in the business of, among other things, manufacturing, marketing, offering for sale, selling, and importing pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, Alvogen has conducted and continues to conduct business in this Judicial District, including the purposeful sale and distribution of drug products.

29. This Court has personal jurisdiction over Lotus, because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through Alvogen; and (2) has maintained extensive and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey, including through, directly or indirectly, Alvogen. This Judicial District is a likely destination for the generic drug product described in Defendants' ANDA.

30. On information and belief, Defendants derive substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) ("API") used in various generic pharmaceutical products sold throughout the United States, including in this Judicial District.

31. On information and belief, Defendants work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products and/or API throughout the United States, including in this Judicial District.

32. On information and belief, both Lotus and Alvogen participated in the preparation and/or filing of ANDA No. 210480.

33. On information and belief, Alvogen serves as the authorized U.S. agent with regards to ANDA No. 210480.

34. On information and belief, Lotus manufactures generic drug products for Alvogen.

35. On information and belief, Alvogen Group, Inc. became the majority shareholder of Lotus in December 2013. Following the transaction, Alvogen and Lotus planned to “collaborate in the important US market, by developing more difficult to produce generic products.” See <http://www.alvogen.com/newsroom/read/alvogen-and-lotus-pharmaceuticals-merge-asian-operations> (last accessed August 25, 2017); see also <http://www.lotuspharm.com/Media/lotus-ir-prezmay17earningsupload1.pdf> (last accessed August 25, 2017) (“Lotus is positioned as a regional platform for Alvogen Group (63.4% holding in Lotus) since Aug 2014 through a reverse merger. . .”).

36. This Court also has personal jurisdiction over Defendants because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and have sent notice of that infringement to Celgene in the State of New Jersey. On information and belief, Defendants intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Celgene in New Jersey and in this Judicial District.

37. In Defendants’ Notice Letter, Defendants stated that the name and address of their agent in the United States authorized to accept service of process for purposes of an infringement action based upon Defendants’ Notice Letter is Andrea Sweet, Vice President Legal Affairs, Alvogen Pine Brook LLC, U.S. Agent for Lotus Pharmaceutical Co., Ltd. Nantou Plant, 10

Bloomfield Avenue, Building B, Pine Brook, NJ 07058. By naming Ms. Sweet as their agent in connection with this action, Defendants have consented to jurisdiction in New Jersey.

38. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Acts Giving Rise To This Suit

39. Pursuant to Section 505 of the FDCA, Defendants filed Defendants' ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 25 mg lenalidomide capsules ("Defendants' Proposed Products"), before the patents-in-suit expire.

40. On information and belief, following FDA approval of Defendants' ANDA, Lotus and Alvogen will work in concert with one another and/or induce one another to make, use, sell, or offer to sell Defendants' Proposed Products throughout the United States, or import such generic products into the United States.

41. On information and belief, in connection with the filing of their ANDA as described above, Defendants provided a written certification to the FDA, as called for by Section 505 of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Defendants' Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Defendants' ANDA.

42. No earlier than July 24, 2017, Defendants sent written notice of their Paragraph IV Certification to Celgene ("Defendants' Notice Letter"). Defendants' Notice Letter alleges that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Defendants' ANDA. Defendants' Notice Letter also informed Celgene that Defendants seek approval to market Defendants' Proposed Products before the patents-in-

suit expire. Defendants specifically directed Defendants' Notice Letter to Celgene's headquarters in Summit, New Jersey, in this Judicial District.

Count I
(Infringement of the '517 Patent)

43. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

44. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '517 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

45. There is a justiciable controversy between the parties hereto as to the infringement of the '517 patent.

46. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '517 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

47. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '517 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '517 patent and knowledge that their acts are encouraging infringement.

48. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '517 patent under 35 U.S.C. §

271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '517 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

49. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '517 patent is not enjoined.

50. Celgene does not have an adequate remedy at law.

51. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II
(Infringement of the '720 Patent)

52. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

53. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '720 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

54. There is a justiciable controversy between the parties hereto as to the infringement of the '720 patent.

55. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '720 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

56. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '720 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '720 patent and knowledge that their acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '720 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '720 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

58. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '720 patent is not enjoined.

59. Celgene does not have an adequate remedy at law.

60. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III
(Infringement of the '977 Patent)

61. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

62. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants'

Proposed Products, prior to the expiration of the '977 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

63. There is a justiciable controversy between the parties hereto as to the infringement of the '977 patent.

64. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '977 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

65. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '977 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '977 patent and knowledge that their acts are encouraging infringement.

66. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '977 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '977 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

67. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '977 patent is not enjoined.

68. Celgene does not have an adequate remedy at law.

69. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV
(Infringement of the '784 Patent)

70. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

71. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '784 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

72. There is a justiciable controversy between the parties hereto as to the infringement of the '784 patent.

73. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '784 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

74. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '784 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '784 patent and knowledge that their acts are encouraging infringement.

75. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '784 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '784 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

76. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '784 patent is not enjoined.

77. Celgene does not have an adequate remedy at law.

78. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V
(Infringement of the '740 Patent)

79. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

80. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '740 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

81. There is a justiciable controversy between the parties hereto as to the infringement of the '740 patent.

82. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '740 patent under 35 U.S.C. § 271(a) by

making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

83. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '740 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '740 patent and knowledge that their acts are encouraging infringement.

84. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '740 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '740 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

85. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '740 patent is not enjoined.

86. Celgene does not have an adequate remedy at law.

87. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI
(Infringement of the '800 Patent)

88. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

89. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '800 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

90. There is a justiciable controversy between the parties hereto as to the infringement of the '800 patent.

91. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '800 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

92. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '800 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '800 patent and knowledge that their acts are encouraging infringement.

93. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '800 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '800 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

94. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '800 patent is not enjoined.

95. Celgene does not have an adequate remedy at law.

96. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII
(Infringement of the '217 Patent)

97. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

98. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '217 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

99. There is a justiciable controversy between the parties hereto as to the infringement of the '217 patent.

100. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '217 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

101. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '217 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants'

ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '217 patent and knowledge that their acts are encouraging infringement.

102. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '217 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '217 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

103. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '217 patent is not enjoined.

104. Celgene does not have an adequate remedy at law.

105. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII
(Infringement of the '569 Patent)

106. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

107. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '569 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

108. There is a justiciable controversy between the parties hereto as to the infringement of the '569 patent.

109. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '569 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

110. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '569 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '569 patent and knowledge that their acts are encouraging infringement.

111. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '569 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '569 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

112. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '569 patent is not enjoined.

113. Celgene does not have an adequate remedy at law.

114. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX
(Infringement of the '886 Patent)

115. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

116. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '886 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

117. There is a justiciable controversy between the parties hereto as to the infringement of the '886 patent.

118. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '886 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

119. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '886 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '886 patent and knowledge that their acts are encouraging infringement.

120. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '886 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to

have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '886 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

121. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '886 patent is not enjoined.

122. Celgene does not have an adequate remedy at law.

123. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count X
(Infringement of the '717 Patent)

124. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

125. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '717 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

126. There is a justiciable controversy between the parties hereto as to the infringement of the '717 patent.

127. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '717 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

128. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '717 patent under 35 U.S.C. §

271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '717 patent and knowledge that their acts are encouraging infringement.

129. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '717 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '717 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

130. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '717 patent is not enjoined.

131. Celgene does not have an adequate remedy at law.

132. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XI
(Infringement of the '498 Patent)

133. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

134. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '498 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

135. There is a justiciable controversy between the parties hereto as to the infringement of the '498 patent.

136. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '498 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

137. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '498 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '498 patent and knowledge that their acts are encouraging infringement.

138. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '498 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '498 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

139. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '498 patent is not enjoined.

140. Celgene does not have an adequate remedy at law.

141. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XII
(Infringement of the '531 Patent)

142. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

143. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '531 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

144. There is a justiciable controversy between the parties hereto as to the infringement of the '531 patent.

145. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '531 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

146. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '531 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '531 patent and knowledge that their acts are encouraging infringement.

147. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '531 patent under 35 U.S.C. §

271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '531 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

148. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '531 patent is not enjoined.

149. Celgene does not have an adequate remedy at law.

150. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIII
(Infringement of the '095 Patent)

151. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

152. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '095 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

153. There is a justiciable controversy between the parties hereto as to the infringement of the '095 patent.

154. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '095 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

155. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '095 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '095 patent and knowledge that their acts are encouraging infringement.

156. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '095 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '095 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

157. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '095 patent is not enjoined.

158. Celgene does not have an adequate remedy at law.

159. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIV
(Infringement of the '120 Patent)

160. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

161. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants'

Proposed Products, prior to the expiration of the '120 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

162. There is a justiciable controversy between the parties hereto as to the infringement of the '120 patent.

163. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '120 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

164. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '120 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '120 patent and knowledge that their acts are encouraging infringement.

165. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '120 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '120 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

166. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '120 patent is not enjoined.

167. Celgene does not have an adequate remedy at law.

168. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XV
(Infringement of the '621 Patent)

169. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

170. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '621 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

171. There is a justiciable controversy between the parties hereto as to the infringement of the '621 patent.

172. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '621 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

173. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '621 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '621 patent and knowledge that their acts are encouraging infringement.

174. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '621 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '621 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

175. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '621 patent is not enjoined.

176. Celgene does not have an adequate remedy at law.

177. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count XVI
(Infringement of the '622 Patent)

178. Celgene repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

179. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation into the United States of Defendants' Proposed Products, prior to the expiration of the '622 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

180. There is a justiciable controversy between the parties hereto as to the infringement of the '622 patent.

181. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will infringe one or more claims of the '622 patent under 35 U.S.C. § 271(a) by

making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States.

182. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will induce infringement of one or more claims of the '622 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, upon FDA approval of Defendants' ANDA, Defendants will intentionally encourage acts of direct infringement with knowledge of the '622 patent and knowledge that their acts are encouraging infringement.

183. Unless enjoined by this Court, upon FDA approval of Defendants' ANDA, Defendants will contributorily infringe one or more claims of the '622 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Defendants' Proposed Products in the United States. On information and belief, Defendants have had and continue to have knowledge that Defendants' Proposed Products are especially adapted for a use that infringes one or more claims of the '622 patent and that there is no substantial non-infringing use for Defendants' Proposed Products.

184. Celgene will be substantially and irreparably damaged and harmed if Defendants' infringement of the '622 patent is not enjoined.

185. Celgene does not have an adequate remedy at law.

186. This case is an exceptional one, and Celgene is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Celgene respectfully requests the following relief:

(A) A Judgment that Defendants have infringed the patents-in-suit by submitting ANDA No. 210480;

(B) A Judgment that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, or importing Defendants' Proposed Products will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 210480 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Defendants and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Defendants' Proposed Products until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing any compounds, solid forms of lenalidomide, compositions, or methods as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Celgene is or becomes entitled;

(F) A Judgment that the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' Proposed Products will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Defendants have committed any acts with respect to the compounds, solid forms of lenalidomide, compositions, or methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Celgene damages for such acts;

(H) If Defendants engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' Proposed Products prior to the expiration of the patents-in-suit, a Judgment awarding damages to Celgene resulting from such infringement, together with interest;

(I) A Judgment declaring that the patents-in-suit remain valid and enforceable;

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Celgene its attorneys' fees incurred in this action;

(K) A Judgment awarding Celgene its costs and expenses incurred in this action; and

(L) Such further and other relief as this Court may deem just and proper.

Dated: September 6, 2017

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter captioned *Celgene Corporation v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 16-7704 (SDW)(LDW) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff and some of the same patents, and because Defendants are seeking FDA approval to market generic versions of the same pharmaceutical product.

I further certify that the matter captioned *Celgene Corporation v. Zydus Pharmaceuticals (USA) Inc., et al.*, Civil Action No. 17-2528 (SDW)(LDW) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff and some of the same patents, and because Defendants are seeking FDA approval to market generic versions of the same pharmaceutical product.

I further certify that the matter captioned *Celgene Corporation v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 17-5314 (SDW)(LDW) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff and some of the same patents, and because Defendants are seeking FDA approval to market generic versions of the same pharmaceutical product.

I further certify that the matter captioned *Celgene Corporation v. Cipla Ltd., et al.*, Civil Action No. 17-6163 (SDW)(LDW) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff and some of the same patents, and because Defendants are seeking FDA approval to market generic versions of the same pharmaceutical product.

I further certify that the matter captioned *Celgene Corporation, et al. v. Lannett Holdings, Inc., et al.*, Civil Action No. 15-697 (SDW)(LDW) (D.N.J.) is related to the matter in

controversy because the matter in controversy involves the plaintiff in this action and some of the same patents, but it does not involve the same pharmaceutical product.

I further certify that the matter captioned *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 17-3387 (ES)(JAD) (D.N.J.) is related to the matter in controversy because the matter in controversy involves the same plaintiff and some of the same patents, but it does not involve the same pharmaceutical product.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 6, 2017

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